K003146

510(k) Summary

NOV 21 2000

1. Submitter:
   DHD Healthcare Corporation
   One Madison Street
   Wampsville, New York 13163

2. Contact:
   Lawrence Weinstein, Director of Technology
   Phone: 315-363-2330 Fax: 315-363-9462

3. Device Name:

Trade name:	Cliniflo™
Common Name:	Flow based incentive spirometer or breathing exerciser
Classification Name:	Incentive Spirometer – 868.5690

4. Predicate Devices:

• Coach 2 (Emerald)	K970596
• Respirex 2	K900754

5. Device Description:
   Cliniflo is a small, single patient use, hand held incentive spirometer intended to encourage deep breathing maneuvers for the post-surgical prevention and treatment of atelectasis.

   The device includes an indicator between two housings. The indicator rises, based upon a users inhalation and provides flowrate feedback to the user. The device also has a rotating knob that adjusts the target flowrate allowing the clinician to fit the needs of the individual patient.

   Additional features of Cliniflo include an oxygen port to allow for simultaneous delivery of oxygen during incentive spirometry therapy, an integral handle and bed-rail hook for ease of handling, and room for instructions to be stored in the base. The device may also incorporate a one way valve, preventing exhalation into the device, keeping the product cleaner and to further encourage use of Cliniflo as an inhalation therapy.

6. Intended Use:
   Cliniflo is indicated for use as an Incentive Spirometer. Proposed claims for Cliniflo include:
   - Cliniflo may be used for the prevention and treatment of atelectasis.
   - Cliniflo may be used to improve clearance of secretions.
   - Cliniflo may be used to facilitate the opening of airways.
   - Cliniflo may be used with supplemental oxygen to reduce patient exposure to non-supplemented oxygen during exercise.

7. Technological Characteristics Compared to Predicate:
   Cliniflo, Coach 2 and Respirex 2 are single patient use plastic devices. All devices contain a flow indicating piston in a housing/tube. The flow piston rises to a certain level during inhalation based upon the flow around the piston and the user's flow rate. Cliniflo has 6

separate flow settings achieved by clinician adjustment of a knob to adjust the leak into the device. Based upon the selected setting, the user can target a specific flow range for therapy. Coach 2 has a single flow window to encourage a single, wider range for an appropriate inhalation rate. Respirex 2 has four labeled steps in one tube to provide feedback and encouragement for inhalation.

In addition, both Coach 2 and Cliniflo include a separate oxygen delivery port which provides oxygen at the ambient air input to the device. Therefore, supplemental oxygen can be provided without changing device performance characteristics.

8. Summary of Studies:
   To verify Cliniflo performance meets specifications, testing was conducted to show Cliniflo accuracy at each setting, representative pressure drop and supplemental oxygen delivery performance. Testing was performed to show that the product meets specifications.

9. Conclusion Drawn from Studies
   Because Cliniflo specifications are the same as, or comparable to, predicate device specifications, the ability of Cliniflo to meet performance specifications demonstrates that Cliniflo raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Lawrence Weinstein
DHD Healthcare Corporation
One Madison Street
Wampsville, NY 13163

Re: K003146
Cliniflo™ Incentive Spirometer
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: October 6, 2000
Received: October 10, 2000

Dear Mr. Weinstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K003146

Cliniflo™ is indicated for use as an Incentive Spirometer and may be used with supplemental oxygen during exercise.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003146

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)